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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,794	09/01/2000	Meir S. Sacks	286262-00005	5973

7590

05/02/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/02/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,794

Applicant(s)

Sacks

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The filing under 1.114 dated 1-27-03 is acknowledged.

Claims included in the prosecution are 1-25. Claims 26-32 remain withdrawn from consideration.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2. Claims 1-6, 8-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder (5,439,938) of record in view of Chobanian et al (6,139,847) of record.**

Snyder discloses compositions containing arginine derivatives, nitroarginine, aminoarginine and methylarginine for the treatment of male sexual dysfunction. The compositions are applied topically in the form of lotions, cremes, salves and ointments (note col. 3, line 10 through col. 4, line 6, Examples and claims). What is lacking in Snyder is the inclusion of an antioxidant.

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Chobanian et al while disclosing a treatment of fibrosis teach that antioxidants such as ascorbate, tocopherol and beta-carotene are NO catabolism inhibitors and advocates the use of the combination of NO stimulators (L-arginine) and NO catabolism inhibitors (note the abstract, col. 3, line 6 through col. 4, line 67, col. 5, line 40, Example 1 and claims). Chobanian further teaches the knowledge in the art of the use of NO donors for the treatment of conditions including impotence (col. 3, lines 6-10).

The inclusion of an antioxidant in the compositions of Snyder would have been obvious to one of ordinary skill in the art, with the expectation of obtaining at least an additive effect, since Chobanian teaches that antioxidants are NO catabolism inhibitors and that they could be used in combination with NO stimulators. Although Snyder does not teach the use of the composition for female sexual dysfunction by topical application to the clitoris, it would have been obvious to one of ordinary skill in the art to use the composition for females with a reasonable expectation of success since clitoris is supplied with blood vessels and the principle of vasodilation is the same.

3. Claims 13-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder (5,439,938) of record in view of Chobanian et al (6,139,847), further in view of Duckett et al (6007,824) by itself or in combination with Wyson (6,031,002) (all are of record).

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The teachings of Snyder and Chobanians have been discussed above. As pointed out above, what is lacking in Snyder is the teachings of the applicability of the arginine derivatives for the treatment of female sexual dysfunction.

Duckett et al as discussed before, disclose compositions containing L-arginine and ginseng (antioxidant) for the treatment female sexual dysfunction. Duckett et al teach that the sexual stimulation causes local release of NO resulting in the smooth muscle relaxation and the increased blood flow. They further teach that L-arginine releases NO resulting in smooth muscle relaxation and increased inflow of blood (note the abstract, col. 1, line 12 through col. 2, line 46, col. 3, line 65 through col. 4, line 50 and claims). The mode of administration in Duckett however, is oral and not topical.

Wysor as discussed before, while disclosing prostaglandin (vasodilator) formulations for enhancing female sexual response teaches that the formulations can be applied topically to the genitals and such a topical treatment is highly effective. Wysor further teaches the use of liposome formulations for the delivery of the composition (note the abstract, columns 1-3 and claims).

In essence, the reference of Duckett shows that the principle of NO release and the increased blood flow in females by the vasodilator, arginine and that of Wysor shows that a vasodialator can be applied topically the genitals to treat female sexual dysfunction.

One of ordinary skill in the art would be motivated further to use the composition of Snyder to treat the female dysfunction since the effectiveness of arginine against female

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dysfunction and that of Wysor shows that a vasodialator composition can be applied topically to the female genitals to achieve the desired goal.

4. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder (5,439,938) of record in view of Chobanian et al (6,139,847) as set forth above, or Snyder (5,439,938) of record in view of Chobanian et al (6,139,847) further in view of Duckett et al (6007,824) by itself or in combination with Wyson (6,031,002) as set forth above, further in view of Quan (6,180,133).

The teaching of Snyder, Chobanian, Duckett, and Wysor have been discussed above. What is lacking in these references is the use of ascorbyl palmitate.

Quan while disclosing topical antioxidant formulations, teaches that ascorbyl palmitate is stable and due to its fat solubility, it penetrates the skin more readily than ascorbic acid reaching comparatively high levels in much shorter periods of time (note col. 5, lines 45-55).

The use of ascorbyl palmitate or ascorbyl palmitate in combination with ascorbic acid would have been obvious to one of ordinary skill in the art since ester form is fat soluble and penetrates the skin more readily as taught by Quan. The use of a mixture would have been obvious since such a use would achieve both rapid slow response times.

Applicant's arguments have been fully considered, but are deemed to be moot in view of these new rejections.

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Applicant's arguments have been fully considered, but are deemed to be moot in view of these new rejections.

Applicant must submit the references on form 1449 to be considered.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 29, 2003